

# DRUG DISCOVERY

## FDA approved drugs - November 2012

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### 1. COMETRIQ (CABOZANTINIB)

#### 1.1. Company

Exelixis, Approved by November 2012

#### 1.2. Treatment Area

Thyroid cancer

#### 1.3. General Information

Cometriq (cabozantinib) is a pan-tyrosine kinase inhibitor. It is specifically approved for the treatment of progressive, metastatic medullary thyroid cancer. It is supplied as a capsule for oral administration. The recommended daily dose is 140 mg (one 80-mg and three 20-mg capsules). It should not be administered with food. Patients should not eat for at least 2 hours before and at least 1 hour after taking Cometriq. Continue treatment until disease progression or unacceptable toxicity occurs.

#### 1.4. Mechanism of Action

Cometriq (cabozantinib) inhibits the tyrosine kinase activity of RET, MET, VEGFR-1, -2 and -3, KIT, TRKB, FLT-3, AXL, and TIE-2. These receptor tyrosine kinases are involved in both normal cellular function and pathologic processes such as oncogenesis, metastasis, tumor angiogenesis, and maintenance of the tumor microenvironment.

#### 1.5. Side Effects

Adverse events associated with the use of Cometriq include: diarrhea, stomatitis, palmar-plantar erythrodysesthesia syndrome, decreased weight, decreased appetite, nausea, fatigue, oral pain, hair color changes, dysgeusia, hypertension, abdominal pain, constipation.

### 2. XELJANZ (TOFACITINIB)

#### 1.1. Company

Pfizer, Approved by November 2012

#### 1.2. Treatment Area

Moderately to severely active rheumatoid arthritis

#### 1.3. General Information

Xeljanz (tofacitinib) is a selective, potent inhibitor of the JAK family of enzymes. Inhibiting these enzymes affects the signaling of multiple cytokines that are involved in a broad spectrum of inflammatory and autoimmune diseases. It is specifically indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs. It is supplied as a tablet for oral administration. The recommended initial dose is 5 mg twice daily, with or without food.

#### 1.4. Mechanism of Action

Xeljanz (tofacitinib) is a Janus kinase (JAK) inhibitor. JAKs are intracellular enzymes which transmit signals arising from cytokine or growth factor-receptor interactions on the cellular membrane to influence cellular processes of hematopoiesis and immune cell function. Within the signaling pathway, JAKs phosphorylate and activate Signal Transducers and Activators of Transcription (STATs) which modulate intracellular activity including gene expression. Tofacitinib modulates the signaling pathway at the point of JAKs, preventing the phosphorylation and activation of STATs.

#### 1.5. Side Effects

Adverse events associated with the use of Xeljanz include: upper respiratory tract infections, headache, diarrhea, and nasopharyngitis.

### 3. FLUCELVAX, INFLUENZA VIRUS VACCINE

#### 3.1. Company

Novartis, Approved by November 2012

#### 3.2. Treatment Area

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## FDA APPROVED DRUGS

Influenza virus subtypes A and type B

### 3.3. General Information

Flucelvax is an inactivated cell-culture-derived vaccine for influenza A and B. Cell-culture manufacturing technology provides an alternative production method to traditional egg-based production, utilizing a well-characterized mammalian cell line rather than chicken eggs to grow virus strains. It is specifically indicated for active immunization in adults aged 18 years and older for the prevention of influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. It is supplied as a solution for intramuscular injection. The recommended dose is a single 0.5 mL intramuscular injection preferably in the region of the deltoid muscle of the upper arm.

### 3.4. Mechanism of Action

Flucelvax is an inactivated cell-culture-derived vaccine for influenza A and B. Cell-culture manufacturing technology provides an alternative production method to traditional egg-based production, utilizing a well-characterized mammalian cell line rather than chicken eggs to grow virus strains.

### 3.5. Side Effects

Adverse events associated with the use of Flucelvax include: injection site pain, injection site erythema, headache, fatigue, myalgia, malaise.